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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

CHANNAVAJALA, LAKSHMI SARADA

ART UNIT PAPER NUMBER

1615

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/661,168

Applicant(s)

AYER ET AL.

Examiner

Lakshmi S Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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DETAILED ACTION

Claims 1-11 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 rejected under 35 U.S.C. 103(a) as being unpatentable over Guittard et al (USPN 5,840,754) in view of Wong et al (USPN 5,082,668).

Instant claims are directed to an osmotic dosage form for delivering 0.5% to 65% of drug and 60% to 99.5% of a hexitol. Dependent claims recite a semi permeable wall surrounding oxybutynin and hexitol and an exit in the wall for delivering the drug. The dependent claims recite specific polyitol and oxybutynin.

Guittard teaches dosage forms comprising oxybutynin and a method for administering the same. Guittard teaches several acceptable salts of oxybutynin such as acetate, hydrochloride, citrate etc (col. 3, lines 34-44), an osmotic solute such as inositol, sorbitol, citric acid etc (col. 3, lines 54-64). The delivery device contains a semi permeable wall surrounding the oxybutynin and osmagent containing core, and a passageway in the wall that connects the exterior of the drug delivery device with the internal compartment (col. 4, lines 41-68). Guittard fails to teach any hexitol or in particular mannitol as an osmagent in the osmotic drug delivery system.

Wong teaches a controlled and continuous, osmotic delivery system comprising a core containing an active agent, a push agent and an osmagent, surrounded by a semi

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permeable membrane and a passageway in the membrane (see col. 3, lines 26-68 and col. 5, lines 31-44; col. 19, lines 62-65). Wong teaches several osmagents including sorbitol, inositol, mannitol etc, at a concentration of 0.01% to 30% or higher (col. 15, lines 38 through col. 16, lines 1-39). Wong teaches the delivery system is useful for delivering highly water soluble as well as poorly water-soluble active agents (col. 20-21).

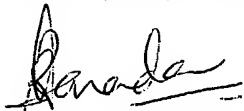
Thus, both Guittard and Wong are directed to controlled release, osmotic drug delivery systems which utilize osmotic solutes or osmagents for the delivery of drugs. While both teach osmagents, Guittard fails to teach hexitol or in particular, mannitol. However, Wong teaches osmagents including mannitol as well as those taught by Guittard i.e., sorbitol, inositol etc., as equally effective in delivering the drug to the exterior, as they all are capable of exhibiting an osmotic pressure gradient across the semi permeable wall. Accordingly, it would have been within obvious for a skilled artisan at the time of the instant invention to use the osmotic agent, mannitol (Wong), or other polyhydric alcohols because Wong teaches that all the osmotic solutes attract fluid into the reservoir producing a solution or a suspension of the drug and deliver concomitantly from the system the dissolved or undissolved drug to the exterior. Thus, one of an ordinary skill in the art would expect that the osmotic solutes such as mannitol result in the successful release of oxybutynin to the exterior, in a controlled and continuous drug delivery due to the dual thermodynamic osmotic activity of the delivery system of Wong. Furthermore, while Wong does not teach the claimed percentages of mannitol, optimizing the amount of mannitol with an expectation to enhance the attraction of fluid in to the reservoir and thus deliver the optimum amount of oxybutynin to the exterior.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
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July 12, 2004